

Notice of Allowability

Application No.

09/542,718

Examiner

Diana B. Johannsen

Applicant(s)

YU ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment, RCE, and IDS of 29 September 2006.
2. ☒ The allowed claim(s) is/are 1-5 and 7-11.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 0906
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date part of 20061215.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Diana B. Johannsen
Primary Examiner
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EXAMINER'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on September 29, 2006 has been entered.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa V. Mueller on December 15, 2006.

Claims 1-5 and 7-11 are now allowed, subject to the Examiner's amendment set forth below. It is noted that the claim set of September 29, 2006 contained a numbering error, in that the claim number "8" was employed twice. The numbering error is corrected in the Examiner's amendment.

3. In accordance with 37 C.F.R. 1.126, allowed claims 1-5 and 7-11 will be renumbered as claims 1-10, respectively (see MPEP 608.01(j)). Original claim numbers are employed in the Examiner's amendment.

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4. The application has been amended as follows.

The following constitutes a complete set of claims incorporating the

Examiner's amendment:

1. (Currently Amended) A combination of nucleic acids comprising a first nucleic acid consisting of the nucleotide sequence SEQ ID NO. 2 and optionally one or more labels, and a second nucleic acid consisting of the nucleotide sequence SEQ ID NO. 3 and optionally one or more labels.
2. (Currently Amended) A combination of nucleic acids for detecting a target sequence comprising a first nucleic acid consisting of the nucleotide sequence SEQ ID NO. 2 and optionally one or more labels, a second nucleic acid consisting of the nucleotide sequence SEQ ID NO. 3 and optionally one or more labels, and a third nucleic acid consisting of a nucleotide sequence selected from the group consisting of SEQ ID NO. 4 and SEQ ID NO. 5, and optionally one or more labels.
3. (Previously Presented) A method of amplifying a $\beta 2$ adrenergic receptor target sequence comprising the steps of:
 - (a) forming a reaction mixture comprising nucleic acid amplification reagents, the combination of nucleic acids of claim 1, and a test sample suspected of containing the target sequence; and
 - (b) subjecting the mixture to amplification conditions to generate at least one copy of the target sequence.
4. (Currently Amended) A method for detecting a target sequence in a test sample comprising the steps of:

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(a) forming a reaction mixture comprising nucleic acid amplification reagents, the combination of nucleic acids of claim 1, and a test sample suspected of containing [[a]] the target sequence;

(b) subjecting the mixture to amplification conditions to generate an amplification product;

(c) hybridizing a probe consisting of a nucleotide sequence selected from the group consisting of SEQ ID NO. 4 and SEQ ID NO. 5, and optionally one or more labels, to the amplification product to form a hybrid; and

(d) detecting the hybrid as an indication of the presence of the target sequence in the test sample.

5. (Currently Amended) A kit for amplifying a $\beta 2$ adrenergic receptor target sequence comprising:

(a) a first nucleic acid consisting of the nucleotide sequence SEQ ID NO. 2 and optionally one or more labels, and a second nucleic acid consisting of the nucleotide sequence SEQ ID NO. 3 and optionally one or more labels; and

(b) amplification reagents.

6. (Canceled).

7. (Currently Amended) The combination of nucleic acids of claim 1, wherein one or more of the nucleic acids ~~incorporates~~ includes said one or more labels.

8. (Currently Amended) The combination of nucleic acids of claim 2, wherein one or more of the nucleic acids ~~incorporates~~ includes said one or more labels.

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[[8]] 9. (Currently Amended) The method of claim 4, wherein the probe ~~incorporates~~ includes said one or more labels.

[[9]] 10. (Currently Amended) The kit of claim 5, wherein the first nucleic acid ~~sequence-incorporates~~ includes said one or more labels.

[[10]] 11. (Currently Amended) The kit of claim 5, wherein the second nucleic acid ~~sequence-incorporates~~ includes said one more labels.

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5. The following is an examiner's statement of reasons for allowance.

It is noted that the claims are now limited to the particular primers and probes exemplified in the specification, which primers and probes are not disclosed in the prior art. The specification demonstrates that these primers and probes can be used to successfully differentiate between wild-type homozygotes, mutant homozygotes, and heterozygotes over a wide range of concentrations (see, e.g., Table 1). One of ordinary skill in the art could not have predicted and would not have expected that these particular probes and primers could be used so successfully. Thus, the prior art does not teach or suggest the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Summary of the Interview of December 15, 2006

6. The examiner contacted applicant's representative to propose minor amendments to the claims that would place them in condition for allowance. The examiner noted that the amendments were required because applicant's dependent claims recited the further inclusion of labels in previously recited nucleic acids that were limited by the use of "consisting of" language (such that the prior claims as written did not allow for the further inclusion of anything, including labels). The examiner noted that as the specification disclosed both labeled primers/probes and primers/probes including one or more labels, the specification inherently disclosed that labels were an optional feature. The examiner proposed amending the claims so as to include the language "and optionally one or more labels." Applicant's representative considered the proposed amendments and contacted the examiner to accept the proposal. Accordingly, claims 1-5 and 7-11 are allowed subject to an Examiner's amendment.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", with a stylized flourish extending to the right.

Diana B. Johannsen
Primary Examiner
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